510(k) Premarket Notification Submission:

JUN - 2 2006

Summary of Safety and Effectiveness

Date of Preparation: December 1, 2005

Submitter Information/ production site:

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Establishment Registration Number:

9611612

Device Information:

Trade Names:	EpiSpin, EpiSpin Set, EpiSpin II Safety Kit
Common Name:	Anesthesia Conduction Kit
Classification Name:	Anesthesia Conduction Kit
Classification Reference:	21 CFR § 868.5140, April 1, 2005,
Poposed Classification:	Regulatory Class II
Proposed Product Classification Code:	CAZ, Kit, Conduction Anesthesia
Panel:	Anesthesiology
Predicate Devices:	1. Pajunks Stimulong Plus Plexus Catheter **K043130, K033018** 2. Pajunks Plexolong Sets **K042979, K023218, K013041** 3. Pajunk Sprotte and various Anesthesia conduction cannulas **K040965, K911202, K911260, K911221** 4. BBrauns Espocan **K932400** (including BBrauns Perifix **K813186)**

Device Description:

Pajunk's EpiSpin set is a single use, sterile, non-pyrogenic and latex free medical device kit. It is a Combined Spinal-Epidural (CSE) anesthesia kit consisting of two needles, one for insertion into the epidural space (a specialized Tuohy Cannula) and one for insertion into the spinal space (a Sprotte Cannula). This needle-through-needle technology is accomplished using an aperture in the curved tip of the specialized Tuohy Cannula (called the "backeye"), for advancement of the Sprotte Cannula into the spinal space. The Spinal needle does not bend at all, but passes easily thru the Tuohy needle. There is no significant friction of metal against metal involved at all.

Predicate Devices:

The devices we claim substantial equivalence with are Pajunks Stimulong Plus Plexus Catheter cleared under **K043130, K033018,** Pajunks Plexolong Sets cleared under **K042979, K023218, K013041** for the whole Kit and cleared kit components and BBrauns Espocan **K932400** (including BBrauns Perifix **K813186**) especially for the Kit components Tuohy Back-Eye and the LOR-Syringe as well as the intended use of the whole Kit.

The detailed discussion of substantial eqivalence can be found in Section 12 of this submission.

Sterilization

The contract sterilizer and the sterilizing process other than a company name change (was IBA Griffith Micro Science, and now is Sterigenics) is the same as that used for anesthesia conduction cannulae cleared for market by FDA under 510(k) number **K040965** and Kit Products Pajunks Stimulong Plus Plexus Catheter **K043130, K033018** Pajunks Plexolong Sets **K042979, K023218, K013041**.

Technology Characteristics:

The **EpiSpin** kit provides needle-through-needle technology, employing the use of a **Tuohy Cannula** featuring a backeye, through which a **Sprotte Cannula** can be inserted in the spinal space for immediate administration of spinal anesthesia. The Sprotte Cannula is then removed, and the **epidural catheter** is then placed for prolonged (up to 72 hours) administration of epidural anesthesia. Safety is optimized by the use of the catheters **fixation adapter**, **Tuohy-Borst adapter**, **flat filter**, **Fixolong catheter fixation device**, and optional **Introducer Aid** provided in the kit.

Conclusion:

The comparison between the predicate devices and the proposed devices in section 12 of this submission demonstrates that the proposed devices are safe and effective, as well as substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2006

Mr. Christian Quass
Regulatory Affairs
Pajunk GmbH Medizintechnologie
Karl-Hall-Strasse 01
78187 Geisingen
GERMANY

Re: K060563
Trade/Device Name: EpiSpin
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: May 19, 2006
Received: May 22, 2006

Dear Mr. Quass:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number: **K060563**

Device Name: **LOR-Syringe**

Indications for Use:

The Pajunk Loss of Resistance (LOR)-Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the Loss of Resistance technique as explained in standard medical textbooks.
These syringes are not intended for injection or aspiration.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

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Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
510(k) Number K060563

Indications for use

510(k) Number: **K060563**

Device Name: **Fixolong Fixation device**

Indications for Use:

The Pajunk Fixolong is an adhesive disk with catheter clips and flat filter attachment point on top. It is employed for fixing the catheter during long term anesthesia conduction.

The adhesive is hypo-allergenic and prevents accidental removal of epidural catheter. The catheter fastening clips allows stabilization of epidural catheter and prevents accidental movement. On the top there is an attachment site for flat filter to protect fixation

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

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Indications for use

510(k) Number: **K060563**

Device Name: **Flat Filter**

Indications for Use:

The Pajunk anesthesia conduction flat filter is a microporous filter used while administering to a patient injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

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Indications for use

510(k) Number: **K060563**

Device Name: **Tuohy Borst Adaptor**

Indications for Use:

The Pajunk Tuohy Borst Adaptor is connected to the needle via Luer connector. It ensures sealing and fixation of the catheter end and allows attachment of a Luer Lock syringe or infusion device.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

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510(k) Number: K060563

Indications for use

510(k) Number: **K060563**

Device Name: **EpiSpin Kits for Anesthesiology**

Indications for Use:

The Pajunk **EpiSpin** anesthesia conduction kit is indicated for administration of regional Combined Spinal-Epidural (CSE) anesthesia. The anesthesia conduction needle is intended for transient delivery of anesthetics to the spinal and epidural space, as well as catheter placement into the epidural space to facilitate a longer anesthetic effect.

After the anesthesia conduction needle has been withdrawn from the patient, the catheter tip can remain in the epidural space for as long as determined by the professional anesthetist and the instructions for use (up to 72 hours).

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

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510(k) Number K060563

Indications for use

510(k) Number: **K060563**

Device Name: **Anesthesia conducting Catheter**

Indications for Use:

The Pajunk catheter is placed in the epidural space to facilitate a longer anesthetic effect.

After the anesthesia conduction needle has been withdrawn from the patient, the catheter tip can remain in the epidural space for as long as determined by the professional anesthetist and the instructions for use (up to 72 hours).

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

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